UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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Eisai Inc., Plaintiff, v. Sanofi-Aventis U.S., LLC, and Sanofi-Aventis, U.S., Inc., Defendants.	CIVIL ACTION NO.: **COMPLAINT** **JURY TRIAL DEMANDED**

This case involves contractual practices by Sanofi-Aventis designed to preserve – and that in fact preserve – its substantial and enduring monopoly in the market for injectable

anticoagulant drugs. Plaintiff, Eisai Inc. ("Eisai" or "Plaintiff") brings this action against Sanofi-Aventis U.S., LLC and Sanofi-Aventis U.S., Inc. ("Sanofi-Aventis") for violations of Sections 1 and 2 of the Sherman Act, Section 3 of the Clayton Act, and the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-3, and § 56:9-4, to bring this anticompetitive conduct to an end.

NATURE OF THE CASE

1. Eisai markets Fragmin®, a type of injectable anticoagulant drug product known as a low molecular weight heparin ("LMWH") that helps to prevent potentially life threatening blood clots in patients with a condition referred to as deep vein thrombosis ("DVT") and to treat patients with symptoms of recurring venous thromboembolism ("VTE"). Fragmin® has been sold in the United States since 1996.

2. Sanofi-Aventis markets an anticoagulant product known as Lovenox®. It has long held monopoly power in the market for the injectable anticoagulant drug products. Sanofi-Aventis accounts for in excess of 90% of all sales for these drugs.

3. Sanofi-Aventis has expanded, protected, and maintained its monopoly power unlawfully, through a variety of anticompetitive means, including exclusionary contracts that draw upon and further protect the monopoly position of Lovenox®. Specifically, Lovenox® contractual provisions require that a hospital customer purchase at least 90% of its relevant injectable anticoagulant purchases from Sanofi-Aventis to avoid losing a discount of up to 30% off the customer's total Lovenox® purchases. (This coercive provision is sometimes referred to below as the "monopoly-share" contractual condition or provision.) Once a hospital's purchases fall below 90%, it forfeits significant discounts. If the customer purchases less than 75% of its requirements from Sanofi-Aventis, the customer receives only a 1% discount. Sanofi-Aventis does not offer the Lovenox® discount without the monopoly-share contractual condition.

4. The only purpose of the monopoly-share condition is to protect and extend Sanofi-Aventis's monopoly power. Any efficiencies or cost-savings that Sanofi-Aventis might claim to achieve by implementing the monopoly-share condition could easily be achieved through other means that do not harm competition.

5. The monopoly-share condition as structured cannot serve to reduce Sanofi-Aventis's costs of distribution or to achieve any other cost-reducing efficiency. The monopoly-share condition cannot serve to facilitate competition within the Relevant Markets (defined below in Paragraphs 52-57) or to facilitate entry into those Markets. There is no legitimate business justification for Sanofi-Aventis's anticompetitive practices and any purported legitimate business justifications are pretexts for these anticompetitive practices.

6. Given Sanofi-Aventis's monopoly, the design of the monopoly-share condition, its evident lack of any procompetitive justification, and its inherent tendency to exclude actual and potential rivals from offering significant competition to Sanofi-Aventis by relegating these rivals to small market shares and denying them the ability to compete effectively across the entire market, the monopoly-share condition is inherently anticompetitive and illegal even absent a showing of specific anticompetitive effects.

7. Nevertheless, the actual anticompetitive effects of Sanofi-Aventis's conduct are real and drastic. Within the Relevant Markets, the monopoly-share condition causes anticompetitive effects in at least two ways. First, it operates as a *de facto* one-way exclusive dealing arrangement. In order to obtain the discount, a hospital must effectively agree to take at least 90% of its requirements from Sanofi-Aventis, thus, effectively placing a cap at 10% on Sanofi-Aventis's anticoagulant competitors' combined sales to hospitals. In this manner, the monopoly-share condition, devoid of any efficiency or procompetitive justification, creates *de*

facto 90% exclusive dealing arrangements across the entire market, resulting in the following anticompetitive effects:

a. Blockading entry by any firm not already in the market by assuring that, after entry, no new entrant could compete for more than 10% of market sales;

b. Forestalling effective competition from Eisai, and other firms already in the market, by imposing barriers to Eisai's expansion of its market share, thereby disabling Eisai from obtaining the same reputational advantages and economies of scale in manufacturing, marketing, and distribution that Sanofi-Aventis enjoys; and

c. Denying consumers unrestricted choice of products; suppressing improvements in patient care; reducing innovation; and prohibiting lower prices, adjusted for quality, that would result from competition on the merits.

8. Second, the monopoly-share condition restricts Eisai's (and other rivals') ability to obtain formulary status at hospitals, which is critical to competition for sales of these anticoagulant products, by erecting a substantial barrier to inclusion in hospitals' formularies. There are a number of factors that enable the monopoly-share condition to create this anticompetitive barrier; these include the facts that: (a) Sanofi-Aventis's Lovenox® already enjoys a 90% market share and is the predominant drug on most hospital formularies; (b) replacing Lovenox® with a new anticoagulant drug within that formulary is costly and time consuming for any hospital; and (c) although Fragmin® and Lovenox® are both approved for a variety of uses, Lovenox® has obtained a comparative stronghold with respect to certain uses. Against this background, the monopoly-share condition operates so that a hospital that wishes to purchase anticoagulant drug products at the lowest price has no effective alternative other than to

purchase at least 90% of its product needs from Sanofi-Aventis. In this manner, the monopoly-share condition, devoid of any efficiency or procompetitive justification, excludes rival anticoagulant sellers from hospitals, resulting in the anticompetitive effects identified above.

9. The actions of Sanofi-Aventis in these respects have had the effect of retaining and enhancing its market power in the Relevant Markets. In fact, this conduct has allowed Sanofi-Aventis to obtain and retain an outright monopoly position, with a market share in excess of 90% in the Relevant Markets.

10. The actions of Sanofi-Aventis have harmed Eisai as well. Eisai offers a product that is clinically competitive with Lovenox® at a competitive price with less restrictive contracting terms. Despite Eisai's significant commercial and clinical investments in the product, Fragmin®'s market-share has remained in the single digits, and currently is approximately 5%. The sales of other anticoagulant competitors have been severely restrained by the conduct of Sanofi-Aventis as well; none of Lovenox®'s other anticoagulant competitors (described below), have been able to obtain market share of over 2%.

11. Sanofi-Aventis's monopoly-share condition previously has been challenged as an antitrust violation. In fact, Sanofi itself (operating as "Organon Sanofi-Synthelabo") challenged these same monopoly-share provisions when Lovenox® was sold by Aventis prior to Sanofi's acquisition of Aventis in 2004. At that time, Sanofi marketed a competing anticoagulant, Arixtra®. Sanofi alleged in its 2003 Complaint that "Aventis is unlawfully monopolizing and restraining competition in certain injectable anticoagulants . . . . The centerpiece of Aventis's illegal conduct is an exclusionary contractual provision that protects the monopoly position of its anticoagulant, Lovenox®." The Complaint further alleged that:

> Aventis is a monopolist in the relevant markets here at issue. Its Lovenox contract operates both as an exclusive-dealing

> arrangement and as a cross-market leveraging arrangement. Aventis is using its monopoly power and the Lovenox contract to exclude competing anticoagulants . . . from the relevant markets, which has the effect of restricting hospital and physician choice and harming patient care.

Sanofi abandoned the Complaint and dismissed the case as a result of its acquisition of Aventis. As part of the acquisition, Organon Sanofi-Syntelabo sold Arixtra® to GlaxoSmithKline.

12. In the present action, Eisai similarly alleges that Sanofi-Aventis's monopoly-share condition constitutes unlawful monopolization and attempted monopolization in violation of Section 2 of the Sherman Act. The Lovenox® monopoly-share provision also constitutes an exclusionary contractual condition of sale in violation of Section 3 of the Clayton Act, an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, and a violation of the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-3, and § 56:9-4.

13. Eisai seeks injunctive relief that prohibits Sanofi-Aventis from imposing or enforcing the Lovenox® monopoly-share contractual provision, or any other similarly exclusionary provision, as a condition for any customer's obtaining a rebate, discount, or other term of sale of Lovenox®. Eisai also seeks treble damages for the injuries it has incurred as a result of Sanofi-Aventis's unlawful conduct.

PARTIES

14. Eisai Inc. is organized and exists under the laws of the State of Delaware. Eisai Inc.'s principal place of business is 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Eisai Inc. markets, sells, and distributes Fragmin® throughout the United States.

15. Sanofi-Aventis U.S., LLC and Sanofi-Aventis U.S., Inc. are subsidiaries of Sanofi-Aventis, a corporation organized and existing under the laws of France, with United States headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S., LLC and Sanofi-Aventis U.S., Inc. are organized and exist under the laws of the State of Delaware.

16. Sanofi-Aventis markets, sells, and distributes pharmaceutical products in this judicial district and throughout the United States. Those products include, but are not limited to, Lovenox®, the injectable anticoagulant that is central to this litigation.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

17. This action arises under the antitrust laws of the United States, including Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 3 of the Clayton Act, 15 U.S.C. § 14, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and under the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-3, 56:9-4, 56:9-10, and 56:9-11.

18. The actions complained of have occurred in and substantially affected interstate commerce as well as commerce in the State of New Jersey.

19. Subject matter jurisdiction with respect to the federal law claims is founded on 28 U.S.C. §§ 1331 and 1337(a). Subject matter jurisdiction with respect to the New Jersey Antitrust Act is founded on 28 U.S.C. § 1367.

20. Sanofi-Aventis may be found, transacts business, and is subject to personal jurisdiction in this judicial district.

21. The violations of law alleged in this Complaint took place, in part, in this judicial district and have injured Eisai in this district. Venue is therefore appropriate in the District of New Jersey.

FACTUAL ALLEGATIONS

Antithrombotic Therapy

22. Deep-vein thrombosis is a condition in which a blood clot develops in the deep veins of the body, most often in the legs. While the formation of a blood clot is generally not life-threatening, the clot can break free and become lodged in the blood vessels of the lungs,

causing a potentially deadly pulmonary embolism ("PE"). DVT and PE collectively are referred to as VTE.

23. Millions of Americans suffer from DVT on an annual basis, and hundreds of thousands experience PE, which can be fatal (resulting in up to 200,000 deaths per year) or cause other serious health problems. Several types of patients are at increased risk for developing DVT, which include surgical patients, orthopedic patients, and oncology patients. Patients undergoing inpatient treatment in a hospital are at increased risk for developing VTE due to decreased mobility during hospitalization.

24. Antithrombotic therapies, such as Fragmin® or Lovenox®, are anticoagulant drug products that reduce the risk of the formation of blood clots in patients with an increased risk of developing VTE. Antithrombotic therapies can also treat patients that already have symptoms of VTE, as well as prevent ischemic complications (reduced blood flow) in patients with unstable angina and non-q-wave myocardial infarction (myocardial infarctions (heart attacks) that generate "q-waves" on an electrocardiogram generally indicate a larger heart attack, where as the absence of q-waves indicate a smaller attack).

25. Most sales of injectable anticoagulant drugs occur in hospitals, or are the result of treatment that first occurred in a hospital and then continued on an outpatient basis or in a long-term care facility. A hospital's formulary, which determines what treatments are available to a patient in a particular hospital, governs most anticoagulant product usage in hospitals.

The Lovenox® Therapeutic Class

26. Sanofi-Aventis's contracts with hospitals for the sale of Lovenox® define the anticoagulant drug products that compete with Lovenox® – and thus are subject to the monopoly-share condition – as the Lovenox® Therapeutic Class ("LTC").

27. The LTC originally consisted of injectable anticoagulants called "low molecular weight heparin" ("LMWH") anticoagulants, or a related form of drug called a "heparinoid." The LMWH products included by Sanofi-Aventis in the LTC are Lovenox®, Fragmin®, and Innohep. In 2002, Sanofi-Aventis expanded the LTC to include Arixtra® – a synthetic injectable anticoagulant introduced that year.

28. These LTC anticoagulants encompass the relevant antitrust product market ("LTC Market") (as discussed below in Paragraphs 52-57).

Lovenox®

29. Lovenox® is a LMWH that is sold by Sanofi-Aventis, administered through injection, and approved by the Food and Drug Administration ("FDA") to prevent blood clotting in connection with the following uses: (1) prophylaxis in hip-replacement surgery; (2) prophylaxis in knee-replacement surgery; (3) prophylaxis in abdominal surgery; (4) prophylaxis in medical patients with severely restricted mobility; (5) treatment for unstable angina and non-q-wave myocardial infarction; (6) treatment of acute ST-segment elevation myocardial infarction; and (7) treatment of patients already suffering from DVT or PE.

30. Lovenox® has been available since 1993.

31. Lovenox® is offered in the following dosage strengths: 30, 40, 60, 80, 100, 120, 150, and 300 mg.

32. Lovenox®'s share of the LTC Market is in excess of 90%. Sanofi-Aventis's 2007 revenues from the sale of Lovenox® in the United States were over $2 billion.

Fragmin®

33. Fragmin® is a LMWH that is sold by Eisai, administered through injection, and approved by the FDA to prevent blood clotting.

34. Fragmin® was launched in the United States in 1996 by Pharmacia. Pfizer acquired Pharmacia in 2003. Eisai obtained the U.S. rights to market Fragmin® from Pfizer in late 2005, and began to sell the product in early 2006.

35. Fragmin®, is approved for numerous indications relating to DVT, which means that it can be widely prescribed to address DVT symptoms. It is approved by the FDA to prevent blood clotting in the following medical settings: (1) prophylaxis in hip-replacement surgery; (2) prophylaxis in abdominal surgery; (3) prophylaxis for unstable angina and non-q-wave myocardial infarction; (4) prophylaxis in medical patients at risk due to limited mobility; and (5) extended-treatment for cancer patients with symptomatic VTE.

36. Fragmin® is the only product in the LTC approved for the extended treatment of symptomatic VTE to reduce the recurrence of VTE in patients with cancer. Cancer patients have a greatly increased risk of VTE because of the hypercoagulable state associated with malignancy, the effects of cancer therapies and surgeries, the prolonged use of central venous catheters, and extended immobility. VTE is second only to cancer itself as the most common cause of death in hospitalized cancer patients.

37. The FDA approved Fragmin®'s indication for the treatment of cancer patients with symptomatic VTE in May 2007, based on a randomized, controlled, open-label clinical trial involving 676 patients. The clinical trial evaluated patients over a six-month period, providing safety and efficacy data regarding the extended use of this LMWH product. Fragmin® is the only product in the LTC with six months of safety and efficacy data regarding its use (in comparison to Lovenox®'s 14-17 days of data from its studies). Fragmin® also is administered in a once-daily dosage for use with oncology patients, which is a significant convenience for cancer

patients undergoing oncology treatment for an extended period, as opposed to a regimen that requires more frequent dosing.

38. Fragmin® is currently offered in dosage forms that include the following: 2,500, 5,000, 7,500, 10,000, 12,500, 15,000, and 18,000 IU pre-filled syringes and 10,000 and 25,000 IU/mL multidose vials (where "IU" refers to an International Unit of "anti-Factor Xa") ("Factor Xa" refers to an activated enzyme that encourages coagulation).

39. Fragmin®'s share of the LTC Market, defined below, is approximately 5%.

40. Fragmin® poses the most acute actual and potential competitive threat confronting Lovenox® today because it is clinically competitive with Lovenox® at a competitive price with less restrictive contract terms.

Innohep

41. Innohep® is a LMWH that was initially marketed by duPont and is now manufactured by Leo Pharma and distributed in the United States by Celgene Corporation. Innohep® is administered through injection and approved by the FDA in connection with treatment of acute DVT with or without PE in conjunction with other medication.

42. Innohep® has been available since July 2000, and is supplied in 2 ml vials containing 20,000 anti-Factor Xa IUs.

43. Innohep®'s share of the LTC Market is approximately 1% or less.

Arixtra®

44. Arixtra® is a synthetic pentasaccharide anticoagulant that is chemically designed to prevent blood clots and is administered through injection. Arixtra® has been marketed since 2002. It was originally marketed by Organon Sanofi-Synthelabo, and currently is sold by GlaxoSmithKline.

45. Arixtra® has been approved by the FDA for the treatment and prophylaxis of VTE in connection with: (1) orthopedic surgery; (2) hip-fracture surgery; (3) abdominal surgery; and (4) the treatment of DVT or PE.

46. Arixtra® is available in the following dosage strengths: 2.5, 5.0, 7.5, and 10.0 mg.

47. Arixtra®'s share of the LTC Market is approximately 2%.

Importance of Hospital Access to Sales of LMWH Anticoagulants

48. Patients generally are initiated on anticoagulant treatment for VTE in hospitals. Approximately 90% of LTC treatment "starts" occur in hospitals, and more than 70% of LTC volume is dispensed in hospitals.

49. A hospital's formulary, which determines what treatments are available to a patient in a particular hospital, governs most LTC product starts. Once a patient receives a particular LTC product in the hospital, that patient – at his/her physician's direction – is likely to remain on the same LTC product while in the hospital in nearly all cases.

50. Patients may continue their anticoagulation treatment after discharge from the hospital, often in long-term care facilities, and sometimes at home. Such patients are likely to remain on the same LTC product initiated in the hospital.

51. As a result of the high share of treatment starts that occur in the hospital, placement on a hospital's formulary for sales of LTC anticoagulants is critical to effective competition. Hospital LTC anticoagulant purchases constitute a sizeable cost and are a significant part of their pharmaceutical budgets. Receipt of the Lovenox® monopoly-share discount is a critical economic consideration for most hospitals purchasing LTC anticoagulants.

THE RELEVANT MARKETS

52. The broadest product market relevant to this action is the market for LMWH anticoagulants and Arixtra®. This market is defined in the Lovenox® contracts as the "Lovenox® Therapeutic Class," and referred to herein as the "LTC Market."

53. LTC anticoagulants were developed more recently than other anticoagulants such as unfractionated heparin and warfarin, and differ significantly from other anticoagulants in numerous ways. Among those differences are that LTC anticoagulants increase the ease of use of the medication, decrease the need to monitor the levels of the medication in the blood, increase the predictability of the anticoagulation effect of the medication over patients and dosage circumstances, and reduce side effects and drug interactions relating to the use of anticoagulation medications.

54. LTC anticoagulants are not reasonably interchangeable with other anticoagulants such as warfarin. An increase in the price of LTC anticoagulants would not attract substitution by other products and would, therefore, be profitable.

55. Substantial barriers to entry inhibit the development of anticoagulants that have characteristics that are similar to those of LTC anticoagulants. Tens of millions of dollars and several years are required for research and development, clinical trials, and FDA approval. Such investments are "sunk," and risky; they cannot be recovered and used for another purpose if the research and development or clinical trials are unsuccessful.

56. The relevant product market also includes certain categories of LTC anticoagulants that are themselves relevant markets. These markets relate to certain medical settings in which LTC anticoagulants are approved by the FDA for use, or are prescribed for use. An increase in price of the products in each of these categories of use would not attract substitution by products approved by the FDA only for other uses and would, therefore, be profitable. These markets include:

- Orthopedic Market: This market comprises various approved indications for orthopedic treatments, including treatment for prophylaxis in hip-replacement surgery and knee-replacement surgery;

- Cardiology Market: This market comprises various approved indications for cardiology treatments, including treatment for unstable angina and non-q-wave myocardial infarction and treatment for treatment of acute ST-segment elevation myocardial infarction;

- Medical Use and Treatment Market: This market comprises various approved indications for certain medical conditions, including treatment for prophylaxis for medical patients with restricted mobility and treatment for patients already suffering from DVT and PE; and

- Oncology Market: This market comprises approved indications for treatment of cancer patients with symptomatic VTE.

These markets are referred to herein as the "Relevant Use Markets." The LTC Market and the Relevant Use Markets are collectively referred to herein as the "Relevant Markets."

57. The relevant geographic markets for the product markets alleged herein constitute the United States and its possessions or territories or such smaller sections or regions of the United States in which the anticompetitive acts or effects complained of herein have occurred or are threatened to occur.

SANOFI-AVENTIS'S LOVENOX CONTRACTING PRACTICES

58. The Lovenox® monopoly-share condition is part of all, or effectively all, contracts pursuant to which hospitals purchase Lovenox®.

59. The monopoly-share condition, as structured, cannot serve to reduce Sanofi-Aventis's costs of distribution or to achieve any other cost-reducing efficiency. The monopoly-share condition cannot serve to facilitate competition within the Relevant Markets or to facilitate entry into those Markets. There is no legitimate business justification for Sanofi-Aventis's anticompetitive practices and any purported legitimate business justifications are pretexts.

60. Sanofi-Aventis has aggressively protected the monopoly position of Lovenox® against competitor penetration in the LTC Market through the monopoly-share condition in its Lovenox® contracts. Sanofi-Aventis has expanded the LTC calculation to cover the attempted

sales of additional anticoagulant competitors following their approval by FDA. Sanofi-Aventis also has increased the discount percentage to fend off competition.

61. For example, in February or March 2002, upon Organon Sanofi-Synthelabo's launch of Arixtra®, Sanofi-Aventis (at that time Aventis, prior to Sanofi's acquisition of Aventis) expanded the LTC to include Arixtra®, increased the monopoly-share discount from approximately 13% to 16.27%, and offered Lovenox® customers an additional 8% in discounts if, and only if, the customer first met the 90% monopoly-share condition.

62. Sanofi-Aventis's current Lovenox® monopoly-share condition requires customers to satisfy both a market size and market share component. Hospitals obtain a maximum discount of up to 30% if they have more than $1,200,000 in LTC purchases, 90% or more of which must be Lovenox® purchases. For LTC purchase shares between 75% to 90%, the discount falls to levels ranging between 9% to 27%. However, if purchase shares drop below 75%, then the discount drops precipitously to 1%.

63. Within the Relevant Markets, the monopoly-share condition causes anticompetitive effects in at least two ways. First, it operates as a *de facto* one-way exclusive dealing arrangement. In order to obtain the discount, a hospital must effectively agree to take at least 90% of its requirements from Sanofi-Aventis, thus, effectively placing a cap at 10% on Sanofi-Aventis's anticoagulant competitors' combined sales to hospitals. This contractual structure deters hospitals from switching to other LTC anticoagulants like Fragmin® or to purchase even a small percentage of their LTC needs from Eisai (or other LTC competitors), even though Eisai offers a product that is clinically competitive with Lovenox® at a competitive price with less restrictive contracting terms.

64. Hospitals already under contract with Sanofi-Aventis face a substantial financial penalty if their LTC purchase share of Lovenox® falls below key thresholds. If sales fall below 90%, hospitals face a penalty of 3% or greater of their discount dollars across all Lovenox® purchases. If sales fall below 75%, hospitals may lose up to 29% of their discounts across all Lovenox® purchases. Thus, the prospect of losing these substantial discounts for potentially modest drops in market share provides a strong deterrent to hospitals from switching to another LTC product, and effectively locks hospitals into buying monopoly quantities of LTC products from Sanofi-Aventis.

65. In this manner, the monopoly-share condition, devoid of any efficiency or procompetitive justification, creates *de facto* 90% exclusive dealing arrangements across the entire market, resulting in the following anticompetitive effects:

a. Blockading entry of any firm not already in the market by assuring that, after entry, no new entrant could compete for more than 10% of market sales;

b. Forestalling effective competition from Eisai, and other firms already in the market, by imposing barriers to Eisai's expansion of its market share, thereby disabling Eisai from obtaining the same reputational advantages and economies of scale in manufacturing, marketing, and distribution that Sanofi-Aventis enjoys; and

c. Denying consumers unrestricted choice of products; suppressing improvements in patient care; reducing innovation; and prohibiting lower prices, adjusted for quality, that would result from competition on the merits.

66. Second, the monopoly-share condition restricts Eisai's (and other rivals') ability to obtain formulary status at hospitals, which is critical to competition for sales of these

anticoagulant products, by erecting a substantial barrier to inclusion in hospitals' formularies. There are a number of factors that enable the monopoly-share condition to create this anticompetitive barrier; these include the facts that: (a) Sanofi-Aventis's Lovenox® already enjoys a 90% market share and is the predominant drug on most hospital formularies; (b) replacing Lovenox® with a different anticoagulant drug within that formulary is costly and time consuming for any hospital; and (c) although Fragmin® and Lovenox® are both approved for a variety of uses, Lovenox® has obtained a comparative stronghold with respect to certain indications.

67. Substantial switching costs are involved in unseating an incumbent – like Sanofi-Aventis – from a hospital's formulary. Obtaining approval to replace a LTC anticoagulant in a hospital's formulary requires a substantial amount of time (often taking months if not years), approval at multiple levels within the hospital, and a significant outlay of administrative resources by both the hospital and pharmaceutical manufacturer. The administrative costs include developing and implementing protocols for the use of an alternate formulary drug; conducting training for medical staff on the use of the new formulary drug; and other measures necessary to fully implement the product in the hospital's clinical, administrative, and financial structures.

68. In addition, Sanofi-Aventis has solidified its monopoly position in certain Relevant Use Markets. In particular, through its various indications relating to cardiology and orthopedic uses, Sanofi-Aventis has obtained a stronghold in the Relevant Use Markets relating to those indications (i.e., the Cardiology Market and Orthopedic Market, described above). Through that monopoly position, Sanofi-Aventis has coerced the use of Lovenox® for other Relevant Use Markets – particularly, the Oncology Market – which has eliminated or effectively

eliminated competition between Sanofi-Aventis and Eisai regarding that market. As a result, consumers and physicians are denied access to the only LTC approved for the extended treatment of symptomatic VTE to reduce the recurrence of VTE in patients with cancer – the only product with six months of safety and efficacy data for the treatment of cancer patients who often undergo long-term treatment.

69. Thus, by conditioning or effectively conditioning a hospital's receipt of the Lovenox® monopoly share discount on sales in the Cardiology Market and/or the Orthopedic Market, Sanofi-Aventis is using its monopoly power in those Relevant Use Markets to acquire, maintain, and/or enhance its monopoly power in additional Relevant Use Markets.

70. In this manner, the monopoly-share condition, devoid of any efficiency or procompetitive justification, excludes rival anticoagulant sellers from hospitals, resulting in the anticompetitive effects described above.

71. In response to Eisai's considerable commercial investment in Fragmin®, Sanofi-Aventis has responded by aggressively enforcing the monopoly-share condition. Furthermore, Sanofi-Aventis's sales representatives have engaged in conduct directly aimed at preventing Fragmin® from being placed on hospitals' formularies. This conduct includes distributing misleading information regarding Eisai's ability to supply Fragmin®, providing misleading information regarding the medical and legal risks involved in hospitals' use of Fragmin®, and suggesting that speaking engagements and/or research grants would be withheld if a hospital places Fragmin® on formulary.

72. The effectiveness of Sanofi-Aventis's Lovenox® contract is demonstrated by its monopoly position – maintained at higher than a 90% market-share – in the LTC Market for approximately a decade or longer, despite the substantial clinical and commercial investments made by Eisai and other competitors in this market.

73. The cumulative effect of Sanofi-Aventis's Lovenox® contracts over the past decade or longer has been to block entry into and to forestall effective competition from other firms already in the LTC Market. Sanofi-Aventis's conduct prevents competition on the merits among Lovenox®, Fragmin®, and other LTC anticoagulants; denies consumers the unrestricted choice among Lovenox®, Fragmin®, and other LTC anticoagulants; suppresses improvements in patient care that would result from unrestricted access to Fragmin®; reduces innovation in the market for LTC anticoagulants; and prohibits lower prices, adjusted for quality, that would result from competition on the merits among all LTC anticoagulants in the Relevant Markets.

THE ANTICOMPETITIVE EFFECTS OF SANOFI-AVENTIS'S ACTIONS

74. Sanofi-Aventis's anticompetitive practices have had a direct, substantial, and adverse effect on competition by monopolizing, and maintaining monopoly power in the Relevant Markets, artificially creating barriers to entry in the Relevant Markets, and foreclosing competition.

75. Sanofi-Aventis's monopoly-share condition is preserving the Lovenox® monopoly in the Relevant Markets by excluding or disabling actual and potential rivals. The Lovenox® monopoly-share condition thereby denies consumers in those Markets – including patients, physicians, hospitals, and long-term care centers – the greater product choice, improved patient care, lower prices, higher quality, and/or increased output that would result from a competitive market structure and from competition unfettered by Sanofi-Aventis's exclusionary conduct.

76. Eisai has been directly and proximately injured by Sanofi-Aventis's unlawful conduct because it has been unreasonably foreclosed from the Relevant Markets. In the absence of the Lovenox® monopoly-share condition, Fragmin®'s growth in the Relevant Markets would be substantially greater than it has been, and will become substantially larger in the future.

Sanofi-Aventis's conduct has deprived Eisai of: (1) past profits; (2) future profits; and (3) the value of invested capital from fruitless efforts to enter and expand in the Relevant Markets.

77. Sanofi-Aventis's foreclosure of Eisai from a substantial portion of the Relevant Markets is injuring, and will continue to injure, Eisai in at least the following ways not adequately remedied by monetary damages in addition to the lost profits alleged above: (1) Eisai is being blocked from obtaining formulary acceptance and physician prescriptions; (2) Eisai's current and prospective customer relationships and good will are impaired; and (3) the brand of Fragmin® is being, and will continue to be, harmed in the Relevant Markets, as the Lovenox® monopoly-share condition creates the appearance that Fragmin® is less effective and safe because it is not widely prescribed.

78. The actual and threatened injuries to the public interest, patient care, and competition in the Relevant Markets that are being caused by Sanofi-Aventis's anticompetitive conduct flow directly from Eisai's injuries and vice-versa. Eisai's injuries are of the type the antitrust laws were designed to prevent, and those injuries flow directly from the aspects of Sanofi-Aventis's conduct that make it unlawful.

NEED FOR INJUNCTIVE RELIEF

79. The Lovenox® monopoly-share condition is currently causing, and will continue to cause, irreparable harm to the public interest, patient care, competition, and Fragmin® in the Relevant Markets in which Fragmin® is currently sold. Those injuries will continue as long as the Lovenox® monopoly-share condition is in place.

80. The injuries to the public interest, patient care, pharmaceutical innovation, and the reputation, good will, and competitive viability of Fragmin® are not susceptible to an adequate remedy through money damages.

81. Continued anticompetitive conduct by Sanofi-Aventis, including the continued enforcement of the Lovenox® monopoly-share condition, and the resulting irreparable injuries to Eisai, Fragmin®, the public interest, patient care, and competition, are imminent. The likelihood of such anticompetitive conduct and resulting injuries warrant the imposition of injunctive relief.

FIRST CLAIM FOR RELIEF
(For Violation of 15 U.S.C. § 2)
Monopolization Of All Relevant Markets

82. Eisai repeats and realleges Paragraphs 1 through 81 as though fully set forth herein.

83. As alleged above, Sanofi-Aventis has monopolized the Relevant Markets in violation of Section 2 of the Sherman Act.

84. Sanofi-Aventis has a market share in excess of 90% and has monopoly power in the LTC Market and each of the Relevant Use Markets.

85. Sanofi-Aventis's monopoly power has been willfully and unlawfully achieved, maintained, and enhanced by imposing the Lovenox® monopoly-share condition on entities purchasing Lovenox® in violation of Section 2 of the Sherman Act. The imposition of the Lovenox® monopoly-share contractual condition in the sale of Lovenox® in the Relevant Markets constitutes exclusionary and unlawful conduct.

86. Sanofi-Aventis, by willfully and unlawfully maintaining a monopoly in the Relevant Markets, is directly and proximately preventing Eisai and other competitors from obtaining a significant, non-trivial share of the Relevant Markets.

87. Sanofi-Aventis's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 63 through 78.

88. As a result of Sanofi-Aventis's conduct, and the harm to competition caused by that conduct, Eisai has suffered substantial and continuing injuries.

SECOND CLAIM FOR RELIEF
(For Violation of 15 U.S.C. § 2)
Attempted Monopolization Of All Relevant Markets

89. Eisai repeats and realleges Paragraphs 1 through 88 as though fully set forth herein.

90. As alleged above, Sanofi-Aventis has attempted to monopolize the Relevant Markets in violation of Section 2 of the Sherman Act.

91. Sanofi-Aventis is violating Section 2 of the Sherman Act by attempting through exclusionary and illegal means, with the specific intent to monopolize, to obtain and/or to maintain a monopoly in the Relevant Markets by imposing the Lovenox® monopoly-share condition on entities purchasing Lovenox®.

92. There is a dangerous probability that Sanofi-Aventis will succeed in unlawfully obtaining and maintaining a monopoly in the Relevant Markets by imposing the Lovenox® exclusionary monopoly-share condition.

93. The imposition of the Lovenox® monopoly-share contractual condition in the sale of Lovenox® in the Relevant Markets constitutes exclusionary and unlawful conduct.

94. Sanofi-Aventis, by unlawfully attempting to obtain and maintain a monopoly in the Relevant Markets, is directly and proximately preventing, and increasingly will prevent, Eisai and other competitors from obtaining a significant and/or non-trivial penetration of the Relevant Markets.

95. Sanofi-Aventis's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 63 through 78.

96. As a result of Sanofi-Aventis's conduct, and the harm to competition caused by that conduct, Eisai has suffered substantial and continuing injuries.

THIRD CLAIM FOR RELIEF
(For Violation of 15 U.S.C. § 14)
Sale On Condition Not To Use Goods Of Competitor And To Force Use Of Full Line Of Lovenox® Goods In All Relevant Markets

97. Eisai repeats and realleges Paragraphs 1 through 96 as though fully set forth herein.

98. As alleged above, Sanofi-Aventis has entered into agreements with purchasers of Lovenox®, whereby Sanofi-Aventis has conditioned the availability of discounts on the condition that the purchasers refrain from purchasing competing products. Each and every contract between Sanofi-Aventis and a purchaser that contained a monopoly-share condition in connection with the purchase of Lovenox® was entered in violation of Section 3 of the Clayton Act. The effect of each agreement is and has been to substantially lessen competition in the Relevant Markets.

99. Sanofi-Aventis, by imposing the monopoly-share condition, is directly and proximately foreclosing Eisai and other competitors from a substantial portion of the Relevant Markets.

100. Sanofi-Aventis's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 63 through 78.

101. As a result of Sanofi-Aventis's conduct, and the harm to competition caused by that conduct, Eisai has suffered substantial and continuing injuries.

FOURTH CLAIM FOR RELIEF
(For Violation of 15 U.S.C. § 1)
Agreements in Restraint of Trade in All Relevant Markets

102. Eisai repeats and realleges Paragraphs 1 through 101 as though fully set forth herein.

103. As alleged above, Sanofi-Aventis has entered into agreements with purchasers of Lovenox® with the purpose and effect of unreasonably restraining trade and commerce in the Relevant Markets.

104. Sanofi-Aventis's solicitation and enforcement of the monopoly-share contractual conditions in the sale of Lovenox® in the Relevant Markets constitute unlawful agreements, contracts, and concerted activity that unreasonably restrain trade in the Relevant Markets in violation of Section 1 of the Sherman Act.

105. Sanofi-Aventis's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 63 through 78.

106. As a result of Sanofi-Aventis's conduct, and the harm to competition caused by that conduct, Eisai has suffered substantial and continuing injuries.

FIFTH CLAIM FOR RELIEF
(For Violation Of The New Jersey Antitrust Act)

107. Eisai repeats and realleges Paragraphs 1 through 106 as though fully set forth herein.

108. Sanofi-Aventis has willfully, knowingly, and with specific intent, unlawfully monopolized commerce, attempted to monopolize commerce, restrained trade, and/or conditioned sales in the Relevant Markets within the State of New Jersey in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-3 and 56:9-4.

109. Eisai sells Fragmin® in the commerce of the State of New Jersey.

110. Sanofi-Aventis, by way of the unlawful conduct complained of herein, is directly and proximately threatening to prevent Eisai from obtaining a significant and nontrivial penetration of the Relevant Markets in which Eisai is a potential competitor, which is directly and proximately threatening to affect the commerce of the State of New Jersey.

111. Sanofi-Aventis has caused, and increasingly will cause, such injuries to Eisai, consumers, and competition as complained of above within the State of New Jersey.

PRAYER FOR RELIEF

WHEREFORE, Eisai respectfully prays that the Court enter judgment against Sanofi-Aventis and in favor of Eisai, as follows:

1. Awarding to Eisai money damages, trebled pursuant to law;
2. Awarding to Eisai the costs of suit, including its reasonable attorneys' fees and court costs;
3. Entering judgment against Sanofi-Aventis and in favor of Eisai, for the following injunctive relief:
    a. Enjoining Sanofi-Aventis from imposing and/or enforcing against Fragmin® the Lovenox® monopoly-share contractual provision, or any other similarly exclusionary provision, as a condition for any customer's obtaining a rebate, discount, or other term of sale of Lovenox®; and
    b. Enjoining Sanofi-Aventis from entering into any agreement regarding the sale (or other disposition) of Lovenox® (or any other product of Sanofi-Aventis that participates or may participate in the Relevant Markets) that attaches any condition of exclusivity, complete, partial, or otherwise, directly or indirectly, for no less than ten (10) years.
4. Ordering such other and further relief as the Court may deem just and proper, and equitable.

JURY TRIAL DEMANDED

Eisai demands a trial by jury for all issues triable by jury.

Dated: August 18, 2008

/s/ *Timothy I. Duffy*

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